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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/013,077	01/26/1998	JEFFREY L. NAUSS		2904
7590	02/19/2004		EXAMINER	
NASH & TITUS, LLC 3415 BROOKEVILLE ROAD SUITE 1000 BROOKEVILLE, MD 20833			CELSA, BENNETT M	
			ART UNIT	PAPER NUMBER
			1639	
			DATE MAILED: 02/19/2004	

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/013,077	NAUSS ET AL.
Examiner	Art Unit	
Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 November 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 15, 18, 21, 22, 25, 26 and 48-54 is/are pending in the application.
- 4a) Of the above claim(s) 18, 53, 54 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 15, 21, 22, 25, 26 and 48-52 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114 (RCE)***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/3/03 has been entered.

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Status of the Claims***

Claims 15, 18, 21-22, 25, 26, 48 and 49-54 are pending.

Claims 18, 53 and 54 are withdrawn from consideration.

Claims 15, 21-22, 25, 26 and 48-52 are under consideration.

### ***Election/Restriction***

2. Applicant's election without traverse of Group I (claims 15, 21-23, 25, 26, 48 and 49 drawn to compositions comprising a 16 amino acid peptide of seq. Id 3) in Paper No.33 is again acknowledged.

3. Newly submitted claims 53 and 54 are directed to an invention that is independent and/or distinct from the invention originally claimed for the following reasons: claim 53 is drawn to "modified" (e.g. analogues, derivatives etc.) synthetic CS3 peptides and claim 54 are drawn to "fragments" of CS3 protein which are patentably distinct from each other and from elected Group I since claims 53 and 54 are drawn to peptides which will possess different amino acid

sequences, physicochemical properties and methods of manufacture and/or use and which will additionally necessitate different and separately burdensome manual and/or computer searches in literature and patent databases. Additionally, separate election of species requirements for claims 53 and 54 will be required for purposes of search.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 53 and 54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Priority***

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

The second application must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the second application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The present application 09/013,077 (filed 1/26/98) claims 35 USC 120 priority (through a string of CIP applications the penultimate being 08/247,884 filed 10/27/95) to 08/064,559 (filed 5/21/93).

Application 08/064,559 fails to provide support for present **claims 50 and 52** insofar that it fails to disclose the claim limitations therein referring to intended minimization of the seq. Id. 3 peptide to effect MHC receptor binding and inhibition of binding HA residues 306-318 nor does the '559 application provide "generic" support for peptides comprising seq. Id 3 (not the protein) found in present claim 52.

***Withdrawn Objection (s) and/or Rejection (s)***

The new matter rejection is hereby withdrawn in view of applicant's amendment and arguments. It is noted that the minimization language of claims 50 and 52 are being interpreted as intended use language which is consistent with ensuring proper claim dependency and claim differentiation.

In light of applicant's claim amendment the rejections of

- a. claims 15, 21-22, 25, 26, 48 and 49 under 35 U.S.C. 103(a) as being unpatentable over Nauss et al. and specification pages 12-13 to demonstrate inherency in view of Reid et al. U.S. Pat. No. 5,417,986 (5/95: filed 4/92 or earlier); and
- b. claims 15, 21-22, 25, 26, 48 and 49 under 35 U.S.C. 102(e) as being anticipated by Reid et al. '986 (5/95: filed 4/92 or earlier) in view of specification pages 12-13 to demonstrate inherency

are hereby withdrawn.

***Outstanding Objection (s) and/or Rejection (s)***

5. Claims 50 and 52 are rejected under 35 U.S.C. 102(a,b) as being anticipated by Nauss et al. Journal of Immunology Vol. 150/No. 8 part II, No. 221 (April 15, 1993) in view of specification pages 12-13 to demonstrate inherency.

The Nauss et al. article teaches a synthetic antigenic T-cell epitope of the pilus protein of enterotoxigenic E. Coli (ETEC) representing residues 63-78 of the ETEC CS3 pilus protein (CS3 63-78) which inhibits the binding of radio-labeled synthetic peptide or residues 307-319 of the influenza hemagglutinin protein (HA 307-319) to purified DR1 Class II MHC in a direct binding assay. The T-cell epitope for CS3 pilus protein subunit 63-78 corresponds to Ser-Lys-Asn-Gly-Thr-Val-Thr-Trp-Ala-His-Glu-Thr-Asn-Asn-Ser-Ala (Seq. Id No: 3) of the CS3 protein, as presently claimed thus rendering the Nauss et al. compositions anticipatory regarding the immunogenic compositions presently claimed. See present specification. Intended use (e.g. minimization, etc.) in compound/composition claims lack patentable weight. Additionally, to the extent that the reference teaching of the reference peptide being "antigenic" fails to suggest immunogenicity; such characteristics would be deemed to be inherent to the reference composition which contain an antigenic peptide and compositions thereof within the scope of the presently claimed invention.

### ***Discussion***

Applicant's argument and change of inventorship were considered but deemed nonpersuasive for the following reasons.

Applicant argues that changing the inventorship of the present application to match the inventorship of the Nauss et al. Article removes this article as being available as prior art under 35 USC 102a. This argument was considered but deemed nonpersuasive regarding claims 50 an 52 which were denied 35 USC 120 priority to the

08/064,559 application for the reasons discussed above under the caption **Priority**.

Thus, the Naus reference is prior art under 35 USC 102(a,b).

Accordingly, the above rejection, as modified is hereby maintained.

6. Claims 15, 21-22, 25, 26 and 48-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,309,669 (10/01).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent claims teach pharmaceutical compositions comprising encapsulated (e.g. biodegradable poly lactide/glycolide) "biologically active agents" including immunogenic (e.g. vaccine) peptides (e.g. antibacterial/antiviral). See e.g. patent claims 1-9. The claims encompass preferred "biologically active agents" which include the CS3 peptide 63-78 corresponding to present sequence id 3 . See col. 32 (especially item "112"); col. 33 (especially item "117"); col. 34 (especially item 133) the selection of which would have been prima facie obvious to one of ordinary skill in the art.

### ***Discussion***

Applicant's arguments directed to the above double patenting rejection were considered but deemed nonpersuasive for the following reasons.

Applicant states that a Terminal Disclaimer was filed with the RCE filing.

This is not persuasive since neither EDAN (scan system) nor PALM indicate receipt and/or processing of the terminal disclaimer.

Accordingly, the above double patenting rejection is hereby maintained.

***Conclusion***

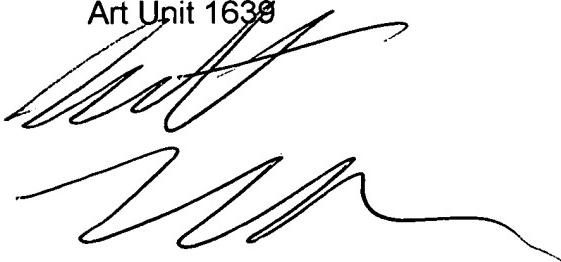
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa  
Primary Examiner  
Art Unit 1639

BC  
February 13, 2004

A handwritten signature in black ink, appearing to read "Bennett Celsa". It consists of two distinct parts: a vertical column of loops and a horizontal flourish at the end.